IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 5 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF DANIEL ELLIOTT, M.D.

Defendants Ethicon, Inc., Ethicon LLC, and Johnson & Johnson (hereinafter "Ethicon") submit this brief in support of their motion to exclude certain general opinions of Daniel Elliott, M.D., as it relates to the cases set forth in Exhibit A to Ethicon's accompanying motion.

Ethicon's brief in this wave of cases is very similar to its brief submitted for the Wave 3 cases, and Ethicon has incorporated herein by reference several aspects of that brief. As set forth herein, Ethicon presents the following arguments that have not previously been argued and/or that have been supplemented with additional authorities: (a) in Section I, Ethicon requests that the Court limit Dr. Elliott's warning opinions consistent with its rulings applicable to other urogynecologists and pelvic surgeons; (b) in Section II, Ethicon requests that the Court preclude Dr. Elliott from comparing Ethicon's devices with traditional surgical procedures consistent with recent rulings by this Court and others; (c) in Section III, Ethicon requests that the Court preclude Dr. Elliott from comparing TVT Secur with other medical devices; (d) in Section VI, this brief highlights a *Daubert* ruling by the United States District for the Northern District of Illinois as it relates to a Wave 1 case remanded from this Court (*see Walker v. Ethicon, Inc.*, 2017 WL 2992301 (N.D. Ill. June 22, 2017)), and (e) in Section XIII, Ethicon requests that the

Court preclude Dr. Elliott from providing opinions about the TVT Exact device because he has not disclosed any opinions about that device, although he has been designated as a general causation expert in at least one case involving only the TVT Exact.

INTRODUCTION

Dr. Elliott is a pelvic surgeon and urogynecologist in Minnesota with experience in the surgical treatment of stress urinary incontinence ("SUI") and pelvic organ prolapse, as well as the removal of sling systems. Ex. B, curriculum vitae. Dr. Elliott intends to provide general opinions about TVT, TVT-O, and TVT Secur (collectively "the TVT Devices") used to treat SUI, as well as Prolift, which is used to treat pelvic organ prolapse. Ex. C-F, Expert Reports. Dr. Elliott's Prolift report also provides general opinions about Gynemesh PS. Ex. F, Prolift Report. As set forth below, the Court should preclude Dr. Elliott from testifying about matters that are beyond his expertise, that are unreliable, that are irrelevant, and/or that are otherwise improper.

LEGAL ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions set forth by the Court in *Huskey v. Ethicon, Inc*., 29 F. Supp. 3d 691, 701 (S.D.W. Va. 2014).

I. The Court should limit Dr. Elliott's product warning opinions.

Dr. Elliott claims that the devices' instructions for use ("IFUs") are not adequate. *See* Ex. C, TVT Report at 31-37; Ex. D, TVT-O Report at 37-40; Ex. E, TVT Secur Report at 36-41; Ex. F, Prolift Report at 52-57. Ethicon requests that the Court confine Dr. Elliott's testimony on this issue in the same manner that it has confined all other urogynecologists and pelvic surgeons.

Specifically, this Court has found that "[w]hile an expert who is an obstetrician and gynecologist may testify about the specific risk of implanting mesh and whether those risks

appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU." *See, e.g., In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig*., 2016 WL 4582220, at *3 (S.D. W. Va. Sept. 1, 2016) (limiting Dr. Bobby Shull); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4536885, at *2 (S.D.W. Va. Aug. 30, 2016) (limiting Dr. Michael Margolis) *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4500767, at *4 (S.D.W. Va. Aug. 26, 2016) (limiting Dr. Jerry Blaivas).

Dr. Elliott's opinions fall squarely within these holdings. Dr. Elliott opines that the IFUs were inadequate because Ethicon did not include information about certain risks. *See, e.g.*, Ex. C, TVT Report at 31-37. However, Dr. Elliott's curriculum vitae does not identify any additional expertise to render an opinion about the adequacy of Ethicon's IFUs, as the Court has required of other experts in this litigation. Dr. Elliott's qualifications as it relates to this topic are no different than the qualifications of the other urogynecologists whose opinions the Court has limited. Accordingly, Ethicon requests that the Court limit Dr. Elliott from testifying about whether specific risks appeared in the IFUs and preclude him from testifying about whether other risks "should or should not be included in an IFU." *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4536885, at *2.

II. The Court should preclude Dr. Elliott from testifying that non-synthetic mesh procedures are a safer alternative.

Dr. Elliott generally takes the position that the Prolene mesh in the TVT Devices and Prolift is unsafe. He opines that autologous slings and Burch colposuspension are safer alternative procedures for the treatment of SUI and that native tissue repair procedures, such as sacrocolpopexy and colporrhaphy, are a safer alternative to Prolift. Ex. C, TVT Report at 8-9;

Ex. D, TVT-O Report at 8-9; Ex. E, TVT Secur Report at 9-10; Ex. F, Prolift Report at 6-7, 56. The Court should exclude these opinions which are irrelevant and unreliable.

A. Dr. Elliott's opinions on this topic are irrelevant.

Any alleged comparative benefits of the traditional approaches to treat SUI and prolapse recommended by Dr. Elliott are not even relevant to Plaintiffs' design defect claims, because these approaches are not a medical device and do not entail altering the design of the devices. Ethicon challenged these opinions in its Wave 1 briefing, and the Court determined that "[t]he relevance of this expert testimony is better decided on a case-by-case basis," and therefore, reserved ruling. *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4500766, at *4 (S.D.W. Va. Aug. 26, 2016). Since that time, however, the Court has issued several rulings suggesting that this should be revisited. First, the Court has determined that opinions about alternative procedures are not a case-specific issue, but instead, an issue within "the province of a general causation expert—not a specific causation expert." *Brooks v. Ethicon, Inc.*, No. 2:12-cv-02865, Mem. Op. at 4 (S.D.W. Va. July 12, 2017), Ex. K hereto.

Second, this Court recently precluded one of Plaintiffs' other general causation experts, Dr. Nathan Goodyear, from offering very similar opinions. In *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2017 WL 1264620, at *3 (S.D.W. Va. Mar. 29, 2017), the Court stated:

> Ethicon argues that Dr. Goodyear's opinions regarding *alternative procedures* are irrelevant to the question of whether a safer alternative design of a product exists. Ethicon states, "[A] medical device *product is* not defective in design simply because alternative surgical and nonsurgical *procedures* may exist." Defs.' Mem. Supp. Mot. 4. ***I agree with Ethicon that alternative procedures/ surgeries do not inform the issue of whether an alternative design for a product exists.*** Accordingly, Ethicon's Motion on this point is **GRANTED** and Dr. Goodyear's alternative procedures testimony is **EXCLUDED**.

(Emphasis added).

Third, in *Mullins v. Johnson & Johnson*, 2017 WL 711766, at *2 (S.D.W. Va. Feb. 23, 2017), the Court explicitly found that "[e]vidence that a surgical procedure should have been used in place of a device is not an alternative, feasible design in relation to the TVT." The Court reasoned that "other surgeries or procedures do not inform the jury on *how* the TVT's design could have feasibly been made safer to eliminate the risks that caused the plaintiffs' injuries." *Id.* (emphasis in original). The Court further found that the "the plaintiffs must provide evidence of an alternative, feasible design for the *product* at issue," which entails "provid[ing] sufficient evidence to identify a comparable product or design concept, whether the *design features* of the comparable product or the *design concept* existing at the time of the [device's] manufacture . . . ." *Id.* at *3 (emphasis in original). *See also Schmidt v. C.R. Bard, Inc.*, 2013 WL 3802804, at *2 (D. Nev. July 22, 2013) ("[N]on-mesh repair is not an alternative design and does not meet Plaintiff's burden to support" a design-defect claim).[1]

Relying on this reasoning, an Illinois federal district court recently precluded another plaintiffs' expert, Dr. Bobby Shull, from testifying that traditional procedures are safer alternatives to the Prolift +M device, stating "[t]he Court agrees with the MDL Court and Defendants that evidence regarding a different surgical procedure not involving mesh is irrelevant to the existence of a safe alternative design for the product at issue in this case." *Walker v. Ethicon, Inc.*, 2017 WL 2992301, at *2 (N.D. Ill. June 22, 2017). The court held as such even though the Illinois law applied in that case did not require the plaintiff to prove the existence of a safer alternative. *See Dunning v. Dynegy Midwest Gen., Inc.*, 2015 IL App. (5th) 140168, ¶66, 33 N.E.3d 179, 197-98 (2015).

[1] These rulings are in accord with others. *See, e.g., Linsley v. C.R. Bard, Inc.*, 2000 WL 343358, *3 (E.D. La. Mar. 30, 2000) (holding that while there existed "alternative techniques" for the mesh surgery, such techniques did not prove an "alternative design" for the polypropylene surgical mesh product). They reflect a general principle of product liability law that applies whenever a safer alternative design is claimed.

The notion that traditional surgical procedures are safer alternatives to Ethicon's devices "really takes issue with the choice of treatment made by [the patient]'s physician, not with a specific fault of" the medical device. *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255 (5th. Cir. 1999)). Notably, **Dr. Elliott fully agrees**. Dr. Elliott has acknowledged that autologous slings and the Burch procedure are not medical devices. Ex. G, 9/26/15 Dep. 23:18-20, 25:3-5, 28:22-24. According to Dr. Elliott: "[W]hen we're talking about safety and complications, it's comparing apples and oranges because there is no medical device placed in those patients that's permanent. . . . Therefore, the bar is changed for the pubovaginal and Burch . . . . So really you can't compare TVT mesh, or any mesh for that matter, and the Burch or autologous fascia for that matter." *Id.* at 74:2-4, 93:18-21, 103:21-22 (emphasis added); *see also id.* at 73:23-24. Thus, Dr. Elliott's opinions about these traditional surgical procedures are not changes to the design feature or the design concept of the device at issue; instead, his opinions would eliminate the device in its entirety. *See also Nease v. Ford Motor Co.*, 848 F.3d 219, 234 (4th Cir. 2017) (finding that controlling case law may "only be read to require the production of evidence on reasonable alternative design, to gauge what 'should have been'") (quoting Restatement (Third) of Torts: Products Liability § 2, Reporter's Note (1998)).

B. Dr. Elliott's comparison of the TVT Devices with traditional surgical procedures is unreliable.

Another reason the Court should preclude Dr. Elliott from comparing the TVT Devices with a traditional surgical procedure is that his opinions are admittedly unreliable. Asked why his expert report did not set forth any opinion about TVT complication rates, Dr. Elliott responded that it was "[b]ecause *we don't know* the true complication rate." Ex. G, 9/26/15 Dep. 196:7-14; *see also id.* at 110:13-17 (emphasis added). For this reason alone, the Court should exclude Dr. Elliott's opinions. Because Dr. Elliott admittedly does not feel qualified to testify

about complication rates, he is not competent to opine that TVT Devices pose a higher risk of complications than non-mesh procedures.

Dr. Elliott's opinions should also be excluded because, rather than relying on medical studies and other sound scientific methodology in support of his opinions as required by *Daubert,* Dr. Elliott improperly relies on a perceived *lack of data* as a basis for his opinions. According to Dr. Elliott, "[t]he data overall with all sling products is very poor," including studies relating to autologous slings, "[a]nd that's why we're in the situation we're in now." *Id.* at 63:11-14, 75:17-76:21; 79:13-14. Dr. Elliott stated that he disagrees with the American Urological Association's ("AUA's") conclusion that synthetic polypropylene mesh has minimal morbidity compared to alternatives, but the basis for his disagreement simply is his belief that "there have been very few randomized control trials, none which are long-term, comparing head-to-head autologous pubovaginal slings versus TVT." *Id.* at 118:19-25; *see also id.* at 123:19-24; 187:21-188:1.

Aside from the fact that Dr. Elliott has a misperception about TVT Device literature, Dr. Elliott improperly infers that this perceived lack of studies demonstrates that the AUA is wrong and that TVT is less safe than alternative surgical approaches. The essence of Dr. Elliott's opinions is that: (a) he is not really sure whether or not TVT Devices are safer than alternative procedures; (b) Ethicon should have conducted additional testing before marketing the devices; and (c) because Ethicon did not do so, he will assume that the TVT Devices are not as safe. This approach is far from trustworthy scientific methodology.

When asked about mesh-related pain, Dr. Elliott conceded: "The true incidence, unfortunately, is not known." Ex. G, 9/26/15 Dep. 261:1-5. He further testified:

> Q. Now, I believe you said that you believe that the long-term dyspareunia rates with the TVT were higher than pubovaginal, did you say, and the Burch?

> A. I don't recall if I mentioned the Burch in there. What I mentioned was the pubovaginal and the Burch have traditionally been a very common procedure done up until the mid-'90s and into probably early 2000's. And in my practice, I have never seen a woman come in with severe pain, life altering pain from either of those aforementioned procedures. But I see it commonly, weekly with the meshes, including the TVT.
>
> Q. You can't point to any comparative trials that show a statistically significantly higher rate of dyspareunia for the TVT retropubic device compared to either the Burch or the pubovaginal sling; correct?
>
> A. Those studies, as you've mentioned, *have not been done*.
>
> Q. And actually, the one paper you pointed me to earlier about the Burch had the 4 percent rate of dyspareunia with that procedure long-term; correct?
>
> A. It wasn't 4 percent. It was 3.9 percent.[2] . . .
>
> Q. Okay. And you can't point to any studies on TVT that show a rate higher than 3.9 percent at that length of follow-up for dyspareunia; can you?
>
> MR. CARTMELL: Object to the form.
>
> A. *Because that study has not been done*. As I mentioned, no studies focused specifically on output -- end point of dyspareunia have been done.

Id. at 327:13-329:2 (emphasis added).

In fact, such studies have been done, and Dr. Elliott has chosen to ignore them. For instance, Heinonen and others performed a 10-year TVT study reporting zero cases of dyspareunia at 10 years follow-up, thus demonstrating that Dr. Elliott's understanding is flat wrong. Ex. H. Dr. Elliott could not recall whether he had reviewed that study. Ex. G, 9/26/15 Dep. at 329:11-21. Nor could Dr. Elliott reconcile his testimony with the AUA guideline and Society of Gynecological Surgeons' meta-analysis and systematic review, both of which reported higher rates of dyspareunia, pain, and sexual dysfunction with the autologous sling and Burch

[2] Dr. Elliott refused to state whether he felt that 3.9% was acceptable. Ex. G, 9/26/15 Dep. 67:21-68:23. This same Burch study upon which Dr. Elliott relied showed an alarming 22% rate of urgency at long term follow up, demonstrating that the procedure is much less efficacious than TVT. *Id.* at 67:4-6; Ex. N.

procedure as compared to mid-urethral mesh devices. *Id.* at 331:20-332:3; Ex. I & J. Even Dr. Elliott's own employer, the Mayo Clinic, advertises that "[u]sing surgical mesh is a safe and effective way to treat stress urinary incontinence." Ex. O.

Dr. Elliott has also arbitrarily discounted literature that he, himself, cites in his report. For instance, when asked about a Cochrane review cited in his own report, (Ex. P; Ex.C, TVT Report at 37 n. 98), Dr. Elliott testified as follow:

> Q. BY MR. SNELL: And this Cochrane Review you cite to in your report does say that "The reported occurrence of problems with sexual intercourse including pain was low" [concerning mesh devices]; correct?
>
> A. That's what they state, yes.
>
> Q. And you didn't acknowledge that point in your report; did you?
>
> A. I talk about dyspareunia in there.
>
> Q. Did you acknowledge that the Cochrane Review that you cite to states that problems with sexual intercourse, including pain, were low in your report?
>
> A. I don't recall using those specific words, no.
>
> Q. Why not?
>
> A. Because, again, this is a meta-analysis of poor quality or moderate quality studies that do not focus on dyspareunia. And specifically they're short-term studies. It does not tell -- also, these are in the hands of experts, high-volume surgeons. Does not tell us the rate of the true average surgeon out there, which is known to be much higher.

Ex. G, 9/26/15 Dep. 111:3-25. In fact, the authors of that Cochrane review upon which Dr. Elliott supposedly relied concluded: "Mid-urethral sling operations have been the most extensively researched surgical treatment for stress urinary incontinence (SUI) in women and have a good safety profile. Irrespective of the routes traversed, they are highly effective in the short and medium term, and accruing evidence demonstrates their effectiveness in the long term.

This review illustrates their positive impact on improving the quality of life of women with SUI." Ex. 4, to 9/26/15 Dep. (Ex.G), at 3.

In *Winebarger v. Boston Scientific Corp.*, 2015 WL 1887222, at *8 (S.D. W. Va. Apr. 24, 2015), this Court noted that "[a]n expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead "selectively [chooses] his support from the scientific landscape." (Citations omitted). Here, Dr. Elliott has achieved the conclusion that he wants to achieve by cherry-picking favorable portions of certain papers while arbitrarily rejecting unfavorable portions of those same papers. In the same manner, he has arbitrarily discounted other studies that do not comport with the opinions he would like to offer in this case. Because Dr. Elliott's failure to account for this literature is not based on any sound scientific principles, his opinions are unreliable and should be excluded.

Finally, the Court should find that Dr. Elliott's personal experiences—unsupported by any trustworthy scientific methodology—fall short of setting forth a reliable foundation for his opinions.[3] In *Winebarger,* this Court found that an expert "may not solely rely on his personal observations, especially when he seeks to provide broad opinions." 2015 WL 1887222, at *10. *See also Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 606 (S.D. W. Va. 2013) (finding that an expert's calculation of complications rates based on his personal experiences "has no basis in any reliable methodology"). Here, Dr. Elliott seeks to offer broad opinions that are based on his personal experiences. Not only are these personal experiences uncorroborated by scientific studies, they are inconsistent with scientific studies. Accordingly, Dr. Elliott's opinions do not satisfy the rigors of *Daubert* scrutiny and should be excluded. Alternatively, the Court should

[3] Dr. Elliott testified about a basic unfamiliarity with autologous sling literature and the experiences of other physicians, stating that "I can't speak to those. I can speak to my own experience." Ex. G, 9/26/15 Dep. 315:24-25; *see also id.* at 316:21-317:18.

reserve ruling on this issue. *See In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab.. Litig.*, 2016 WL 4500766, at *4 (S.D. W. Va. Aug. 26, 2016).

III. The Court should preclude Dr. Elliott from comparing TVT Secur with other medical devices.

For similar reasons, the Court should not allow Dr. Elliott to suggest that TVT, TVT-O and/or other devices were safer, feasible alternative devices to TVT Secur. In his TVT Secur general report, Dr. Elliott states that "the best course of action is to avoid using polypropylene mesh in the pelvic floor" and that "traditional surgical repairs" are a safer alternative. Ex. E, TVT Secur Report at 36. However, he also states that "TVT and TVT-O had far better success rates that the TVT-S," thus suggesting that he intends to testify that TVT and TVT-O were safer alternatives. *Id.*

In response to deposition questioning, however, Dr. Elliott definitively clarified that he believes that all mid-urethral mesh slings are "unsafe." Ex. G, 9/26/15 Dep. 143:11-14, 144:16-18. According to Dr. Elliott, "[m]esh should not be placed in the vagina," period. *Id.* at 285:22. Quite simply, Dr. Elliott should not be permitted to suggest that other mesh products offer a safer alternative to TVT Secur given that he is unwilling to stand behind the alternative and confirm that it is safe and effective in treating SUI. Indeed, Dr. Elliott's TVT and TVT-O general reports reveal that he unequivocally believes that those devices are unsafe. Ex. C, TVT Report; Ex. D, TVT-O Report. Dr. Elliott may not be permitted to tell one jury that TVT is unsafe, and then turn around and tell another jury that it was a suitable, safer alternative to TVT Secur.

In addition, courts have found that products may not be compared with other products that have different advantages and disadvantages even if they share the same general purpose. *See, e.g. Linegar v. Armour of Am., Inc.*, 909 F.2d 1150 (8th Cir. 1990) (bullet-proof vest could not be compared with a bullet-proof coat). This "same product" requirement is especially

important where the different product requires a different type of surgery. Each surgery has different purposes because it carries its own risks and benefits. For the surgeon, those may depend not only on the characteristics of the surgery but also on individual experience and training. And, in the end, each surgeon operates based on his or her own choices, experience, and judgment. In the pedicle screw cases, for instance, the courts repeatedly, and unanimously, rejected alternative designs that consisted of a different kind of spine surgery using hooks and wires. *See Talley v. Danek Med.*, 179 F.3d 154, 162 (4th Cir. 1999); *see also Hosford v. BRK Brands, Inc.*, -- So. 3d --, 2016 WL 4417256, at *6 (Ala. 2016) (rejecting argument that design of a dual-sensor fire alarm marketed by the manufacturer defendant was an alternative design to an ionization fire alarm as "it is a design for a different product altogether"); *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 385 (Tex.1995) (noting in design defect context that "[a] motorcycle could be made safer by adding two additional wheels and a cab, but then it is no longer a motorcycle" and that product liability law does not "impose liability in such a way as to eliminate whole categories of useful products from the market"); *Brockert v. Wyeth Pharm. Inc.*, 287 S.W. 3d 760, 770-71 (Tex. Ct. App. 2009) (a different drug with the same general purpose is not an alternative design).

It is one thing for Dr. Elliott to opine that TVT Secur could be designed differently by containing a different type of mesh. It is an entirely different thing, however, for Dr. Elliott to take issue with Plaintiffs' implanting physicians' choice to recommend a particular medical device rather than another device. Each device carries with it its own advantages and disadvantages and the surgeon's selection of the device depends on a number of factors beyond Ethicon's control, including the experience and training of the physician, which is why the law

trusts the physician with that decision and does not make the decision for him by allowing a jury to substitute its judgment.

Finally, Dr. Elliott's opinions on this topic should also be excluded on the basis that they are unreliable for the reasons set forth in Section II.B above.

IV. The Court should preclude Dr. Elliott from testifying that a device with lighter weight, larger pore mesh would serve as a safer alternative.

Ethicon adopts its Wave 3 argument on this issue set forth in Section II.B of Doc. 2815.

V. The Court should preclude Dr. Elliott from criticizing the cut of TVT mesh.

Ethicon adopts its Wave 3 argument on this issue set forth in Section III of Doc. 2815.

VI. The Court should not allow Dr. Elliott to speculate about the duties of a medical device manufacturer.

In his reports, Dr. Elliott criticizes Ethicon for allegedly failing to comply with certain duties owed by a medical device manufacturer. Dr. Elliott is not qualified to provide such testimony, and his opinions are unreliable.

A. Research/Testing

Dr. Elliott faults Ethicon for allegedly not performing certain testing and conducting studies. *See, e.g.*, Ex. C, TVT Report at 29, 33-34, 37; Ex. D, TVT-O Report at 30-31, 35-36, 40-41; Ex. E, TVT Secur Report at 25-28, 43; Ex. F, Prolift Report at 13, 53, 55; Ex. G, 9/26/15 Dep. 240:17-19, 259:8-10, 271:9-16, 275:4-9, 303:21-23. The Court should exclude these opinions, which are of questionable relevance, because Dr. Elliott is not competent to testify about the level of testing that a manufacturer, such as Ethicon, should have performed.

As an initial matter, a lack of testing or a flaw in the design process is not, standing alone, a design defect. *See, e.g., Green v. General Motors Corp.*, 310 N.J. Super. 507, 529 (App. Div. 1998) ("[A] product that is not defective and has not been tested at all remains free of a defect").

The "failure to test" claim here should be seen for what it is—a transparent attempt to shift the burden to the *defendant* to prove the absence of the defect when the plaintiff cannot carry her burden to prove the existence of a defect.

Even if the degree of testing were relevant, there is nothing in Dr. Elliott's background that would provide him with specialized knowledge about the testing that Ethicon or other medical device manufacturers supposedly should have performed. He has never manufactured or even worked on the design of a medical device, much less had any involvement with FDA clearance of a medical device. Dr. Elliott's resume does "not include knowledge or even experience in the manner in which corporations and the [medical device] marketplace react, behave or think regarding their non-scientific goals of maintaining a profit-making organization that is subject to rules, regulations, standards, customs and practices among competitors and influenced by shareholders or public opinion." *In re Diet Drugs Prods. Liab. Litig.*, 2000 WL 876900, at *9 (E.D. Pa. June 20, 2000).

Because Dr. Elliott has no relevant experience, he is unable to identify a single rule or regulation that would require Ethicon to conduct different testing. Moreover, Dr. Elliott does not identify *any* basis or reason for these opinions, as he must. Instead, his opinion apparently is based purely on unscientific personal belief. When asked about how certain studies/testing should be conducted, Dr. Elliott responded that he did not know. *See, e.g.*, Ex. G, 9/26/15 Dep. Tr. 259:17-21 ("The basic unfortunate reality is it – I don't know if it could be done").

Further, a fundamental problem with Dr. Elliott's opinion that Ethicon should have conducted additional testing and studies before marketing the devices is that Dr. Elliott can only speculate about what those results would have shown. Thus, as noted by one court, "imposition of liability for breach of an independent duty to conduct long-term testing, where the causal link

to the known harm to plaintiff is the *unknown outcome of testing that was not done*, would be beyond the pale of any California tort doctrine we can identify." *Valentine v. Baxter Healthcare Corp.*, 68 Cal. App. 4th 1467, 1486 (1999) (emphasis in original).

This Court has consistently precluded other surgeons from testifying about this issue. In its Wave 1 rulings, the Court found that "[t]here is no indication that Dr. [Bruce] Rosenzweig has any experience or knowledge on the appropriate testing a medical device manufacturer should undertake." *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig*., 2016 WL 4500765, at *5 (S.D.W. Va. Aug. 26, 2016); *see also Huskey v. Ethicon, Inc*., 29 F. Supp.3d 691, 705 (S.D.W. Va. July 8, 2014) (finding that "there is no indication that [plaintiff's pelvic surgeon expert] has any experience or knowledge on the appropriate testing a medical device manufacturer should undertake"); *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, at *15 (S.D.W. Va. Apr. 28, 2015) (finding that because pelvic surgeon "has no demonstrated training in, knowledge about, or experience with the design of clinical trials or the process of testing medical devices, his opinion falls short of Federal Rule of Evidence 702 and cannot be admitted"). Further, the Court has determined that "[w]hether Ethicon studied certain issues, provided information, or provided guidance are all examples of corporate conduct." *Bellew v. Ethicon, Inc*., 2014 WL 12685965, at *9 (S.D. W. Va. Nov. 20, 2014).

Recently, another federal district court, on remand from this Court, agreed with this Court's reasoning and precluded Dr. Bobby Shull from testifying about research and testing, finding that "Plaintiffs have not shown that Dr. Shull is qualified to testify regarding the standard of care for medical device testing," and that his opinions about the extent of testing "would merely address facts found in corporate documents." *Walker v. Ethicon, Inc.*, 2017 WL 2992301, at *5 (N.D. Ill. June 22, 2017). *See also In re: Silicone Gel Breasts Implants Prod.*

Liab. Litig., 318 F. Supp. 2d 879, 901-02 (C.D. Cal. Apr. 22, 2004) (finding that a chemist was not qualified to criticize defendants' alleged lack of testing and noting that "Plaintiff proffers no evidence that [the expert] has any experience developing an implantable medical device for general use or that he has any foundational knowledge about what standard practices exist in the industry in this regard").

For these reasons, the Court should preclude Dr. Elliott from offering such testimony in these cases. *See also Hovey v. Cook, Inc.*, 2015 WL 1405565, at *11 (S.D. W. Va. Mar. 26, 2015) (noting in *Daubert* ruling that "plaintiff concedes that 'Dr. Elliott will not testify that defendant had an obligation to study and failed to do so'").

B. Adverse Event Reporting

Dr. Elliott also claims that Ethicon "fail[ed] to properly evaluate and act in response to adverse event reports." Ex. F, Prolift Report at 55. Dr. Elliott's experience as a urologist does not qualify him to render opinions on adverse event collection and reporting. He has no relevant experience with the FDA or in the medical device industry that would permit him to offer expert testimony regarding the standard of care for collecting and reporting adverse events. *See, e.g., In re Diet Drugs*, MDL No. 1203, 2001 WL 454586, *16 (E.D. Pa. Feb. 1, 2001) (excluding heart surgeon's opinions regarding adverse event reporting because surgeon had "no experience or expertise in . . . adverse event reporting" and based his opinions on personal belief rather than reliable methodology).

In its Wave 1 ruling, this Court found that "opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations are **EXCLUDED.**" *In re: Ethicon, Inc.*, 2016 WL 4500766, at *5. The Court should do so again here and clarify that all of Dr. Elliott's adverse event reporting opinions are excluded, regardless of whether they are

specific to compliance with FDA regulations. In *Walker, supra,* the Illinois federal district court prevented Dr. Shull from providing similar criticisms of Ethicon's response to adverse event reports. *Walker,* 2017 WL 2992301, at *6. According to the court, "[s]imilar to the MDL Court excluding Dr. Shull's opinion regarding product testing or clinical trials in another case based on a lack of experience with such matters, *see Carlson*, 2015 WL 1931311, at *15, the Court excludes Dr. Shull's opinion regarding the standard of care for adverse event reporting because Plaintiffs have not demonstrated that Dr. Shull has relevant experience to testify as an expert about this matter." *Id.* The court further "note[d] that Dr. Shull cannot serve as a conduit for corporate information by testifying about the extent of Defendants' adverse event reporting." *Id.*

C. Training

In his Prolift and TVT Secur Reports**,** Dr. Elliott also claims that Ethicon did not provide appropriate training to physicians. Ex. E, TVT Secur Report at 41-43; Ex. F, Prolift Report at 42-46. Dr. Elliott is not qualified to opine about the level of training that a manufacturer is required to provide, and he admitted that he never participated in any Prolift training. Ex. L, Elliott Nov. 15, 2012 Dep. Tr. 113:3-8; Ex. M, Elliott Nov. 16, 2012 Dep. Tr. 387:11-21. Further, these opinions are irrelevant insofar as Dr. Elliott has not claimed that Plaintiffs' implanting physicians were inadequately trained. *See Cisson*, 948 F. Supp. 2d at 614 (excluding similar opinions about training under similar circumstances). Consistent with the Illinois federal court's ruling in *Walker, supra,* the Court should determine that any of Dr. Elliott's opinions about training should be limited to a discussion of "the risks of implanting mesh and whether Defendants' product materials raise those risks, but he may not offer testimony about 'what information should or should not be included in an [Instructions for Use]' or other similar materials." *Walker,* 2017 WL 2992301, at *6.

VII. The Court should preclude Dr. Elliott from testifying about alleged mesh degradation, shrinkage, contraction, and other biomaterials opinions.

Ethicon adopts its Wave 3 argument on this issue set forth in Section V of Doc. 2815.

VIII. The Court should prevent Dr. Elliott from providing general opinions about TVT Exact.

Dr. Elliott has prepared general reports in these waves of cases only for certain devices, but he has not prepared a report for TVT Exact. Although one set of the Plaintiffs in Exhibit A to Defendants' motion—Carla and Edward Eason—designated Dr. Elliott as a general causation expert, she was implanted with a TVT Exact device and not a device in which Dr. Elliott has disclosed an opinion. No. 2:12-cv-7909, Doc. 1, ¶8. Because Plaintiffs have not disclosed any opinions of Dr. Elliott related to the TVT Exact, they should not be allowed to elicit general causation opinions from him about this product. *See* Fed. R. Civ. P. 26(a)(2)(B)(i); *Lewis v. Ethicon, Inc.*, 2014 WL 186872, at *17 (S.D. W. Va. Jan 15, 2015) ("Under Rule 26, expert reports must contain 'a complete statement of all opinions the witness will express and the basis and reasons for them'").

IX. The Court should not allow other opinions beyond Dr. Elliott's expertise and/or that are otherwise improper.

Ethicon adopts its Wave 3 argument on this issue set forth in Section VI of Doc. 2815.

CONCLUSION

For the foregoing reasons, the Court should limit Dr. Elliott's testimony in these cases.

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 5 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on this date, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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